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IDENTIFICATION CODES

c—Cited
cd—Clinical dialogue
efm—EFM today
et—Equal time

le—Editorial
nl—News from the literature
oa—Original article
pr—Protocol

ppc—Problem-patient
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TICAR[®] (Sterile Ticarcillin Disodium) for Intramuscular or Intravenous Use

For complete prescribing information, consult official package insert.

ACTIONS: Ticarcillin is bactericidal; it is not absorbed orally, therefore, it must be administered intravenously or intramuscularly.

INDICATIONS: TICAR (Ticarcillin Disodium) is indicated for the treatment of the following infections:

- Bacterial septicemia†
- Skin and soft-tissue infections†
- Acute and chronic respiratory tract infections†‡
- †caused by susceptible strains of *Pseudomonas aeruginosa*, *Proteus* species (both indole-positive and indole-negative) and *Escherichia coli*.
- ‡Though clinical improvement has been shown, bacteriological cures cannot be expected in patients with chronic respiratory disease or cystic fibrosis.
- Genitourinary tract infections (complicated and uncomplicated) due to susceptible strains of *Pseudomonas aeruginosa*, *Proteus* species (both indole-positive and indole-negative), *Escherichia coli*, *Enterobacter* and *Streptococcus faecalis* (enterococcus).

Ticarcillin is also indicated in the treatment of the following infections due to susceptible anaerobic bacteria:

- (1) Bacterial septicemia.
- (2) Lower respiratory tract infections such as empyema, anaerobic pneumonia and lung abscess.
- (3) Intra-abdominal infections such as peritonitis and intra-abdominal abscess (typically resulting from anaerobic organisms resident in the normal gastrointestinal tract).
- (4) Infections of the female pelvis and genital tract such as endometritis, pelvic inflammatory disease, pelvic abscess and salpingitis.
- (5) Skin and soft-tissue infections.

Although Ticarcillin is primarily indicated against Gram-negative infections, its *in vitro* activity against Gram-positive organisms should be considered in treating infections caused by both Gram-negative and Gram-positive organisms.

Based on the *in vitro* synergism between Ticarcillin and gentamicin sulfate or tobramycin sulfate against certain strains of *Pseudomonas aeruginosa*, combined therapy has been successful, using full therapeutic dosages.

Culturing and susceptibility testing should be performed initially and during treatment.

CONTRAINDICATIONS: A history of allergic reaction to any of the penicillins is a contraindication.

WARNINGS: Anaphylaxis may occur, especially in patients with an allergic diathesis. Check for a history of allergy to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, the drug should be discontinued unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to Ticarcillin therapy. Serious anaphylactic reactions require immediate emergency treatment with epinephrine, oxygen, intravenous steroids and airway management.

Some patients receiving high doses of Ticarcillin may develop hemorrhagic manifestations associated with abnormalities of coagulation tests. Patients with renal impairment, in whom excretion of Ticarcillin is delayed, should be observed for bleeding manifestations. Such patients should be dosed strictly according to recommendations. If bleeding manifestations appear, Ticarcillin treatment should be discontinued and, if necessary, appropriate therapy instituted.

PRECAUTIONS: During prolonged treatment, periodic checking for organ system dysfunction (renal, hepatic and hematopoietic) is advisable. If overgrowth of resistant organisms occurs, the appropriate therapy should be initiated.

Since the theoretical sodium content is 5.2 milliequivalents (120 mg) per gram of Ticarcillin, electrolyte and cardiac status should be monitored carefully.

In a few patients receiving intravenous Ticarcillin, hypokalemia has been reported. Serum potassium should be measured periodically.

USAGE DURING PREGNANCY: Reproduction studies have been performed in mice and rats and have revealed no evidence of impaired fertility or harm to the fetus due to Ticarcillin. There are no well-controlled studies in pregnant women, but investigational experience does not include any positive evidence of adverse effects on the fetus. Although there is no clearly defined risk, such experience cannot exclude the possibility of infrequent or subtle damage to the fetus. Ticarcillin should be used in pregnant women only when clearly needed.

ADVERSE REACTIONS: The following adverse reactions may occur: skin rashes, pruritus, urticaria, drug fever, nausea, vomiting, anemia, thrombocytopenia, leukopenia, neutropenia, eosinophilia. SOD† and SGPT† elevations have been reported. Patients, especially those with impaired renal function, may experience convulsions or neuromuscular excitability when very high doses of the drug are administered.

Local reactions at the site of injection have been reported. Vein irritation and phlebitis can occur, particularly when undiluted solution is directly injected into the vein.

DOSAGE AND ADMINISTRATION: Usual adult recommended dosage in bacterial septicemia, respiratory tract infections, skin and soft-tissue infections, intra-abdominal infections and infections of the female pelvis and genital tract, is 3 grams by intravenous infusion every 3, 4 or 6 hours depending on weight and severity of infection; in uncomplicated urinary tract infections, 1 gram I.M. or direct I.V. q.i.d.; in complicated urinary tract infections, 3 grams q.i.d. by I.V. infusion.

Please consult official package insert for details on dosages for patients with renal insufficiency, children, neonates and directions for use.

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- 1 Gm, 3 Gm and 6 Gm Standard Vials
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Ponstel® (mefenamic acid)

Before prescribing, please see full prescribing information. A Brief Summary follows:

INDICATIONS AND USAGE: Ponstel is indicated for the relief of moderate pain when therapy will not exceed one week. Ponstel is also indicated for the treatment of primary dysmenorrhea.

Studies in children under 14 years of age have been inadequate to evaluate the safety and effectiveness of Ponstel.

CONTRAINDICATIONS: Ponstel should not be used in patients who have previously exhibited hypersensitivity to it.

Because the potential exists for cross-sensitivity to aspirin or other nonsteroidal antiinflammatory drugs, Ponstel should not be given to patients in whom these drugs induce symptoms of bronchospasm, allergic rhinitis, or urticaria.

Ponstel is contraindicated in patients with active ulceration or chronic inflammation of either the upper or lower gastrointestinal tract.

Ponstel should be avoided in patients with preexisting renal disease.

WARNINGS: In patients with a history of ulceration or chronic inflammation of the upper or lower gastrointestinal tract, Ponstel should be given under close supervision and only after consulting the Adverse Reactions Section.

If diarrhea occurs, the dosage should be reduced or temporarily suspended (see Adverse Reactions and Dosage and Administration). Certain patients who develop diarrhea may be unable to tolerate the drug because of recurrence of the symptoms on subsequent exposure.

PRECAUTIONS: If rash occurs, administration of the drug should be stopped.

A false-positive reaction for urinary bile, using the diazo tablet test, may result after mefenamic acid administration. If bilirubin is suspected, other diagnostic procedures, such as the Harrison spot test, should be performed.

In chronic animal toxicity studies of Ponstel at doses 7 to 28 times the recommended human dose, rats had minor microscopic renal papillary necrosis, dogs had edema and blunting of the renal papilla, and monkeys had renal papillary edema. Normal human volunteers had mild BUN elevations with prolonged administration at greater than therapeutic doses. The significance of these findings is unknown. However, since Ponstel is eliminated primarily through the kidneys, the drug should not be administered to patients with significantly impaired renal function.

Information for Patients: Patients should be advised that if rash, diarrhea or other digestive problems arise, they should stop the drug and consult their physician.

Patients in whom aspirin or other nonsteroidal antiinflammatory drugs induce symptoms of bronchospasm, allergic rhinitis, or urticaria should be made aware that the potential exists for cross-sensitivity to Ponstel.

The long-term effects, if any, of intermittent Ponstel therapy for dysmenorrhea are not known. Women on such therapy should consult their physician if they should decide to become pregnant.

Drug Interactions: Ponstel may prolong prothrombin time. Therefore, when the drug is administered to patients receiving oral anticoagulant drugs, frequent monitoring of prothrombin time is necessary.

Use in Pregnancy: Pregnancy Category C. Reproduction studies have been performed in rats, rabbits and dogs. Rats given up to 10 times the human dose showed decreased fertility, delay in parturition, and a decreased rate of survival to weaning. Rabbits at 2.5 times the human dose showed an increase in the number of resorptions. There were no fetal anomalies observed in these studies nor in dogs at up to 10 times the human dose.

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used only if clearly needed.

The use of Ponstel in late pregnancy is not recommended because of the effects on the fetal cardiovascular system of drugs of this class.

Nursing Mothers: Trace amounts of Ponstel may be present in breast milk and transmitted to the nursing infant. Thus Ponstel should not be taken by the nursing mother because of the effects on the infant cardiovascular system of drugs of this class.

Use in Children: Safety and effectiveness in children below the age of 14 have not been established.

ADVERSE REACTIONS: Gastrointestinal: The most frequently reported adverse reactions associated with the use of Ponstel involve the gastrointestinal tract. In controlled studies for up to eight months, the following disturbances were reported in decreasing order of frequency: diarrhea (approximately 5% of patients), nausea with or without vomiting, other gastrointestinal symptoms, and abdominal pain.

In certain patients, the diarrhea was of sufficient severity to require discontinuation of medication. The occurrence of the diarrhea is usually dose related, generally subsides on reduction of dosage, and rapidly disappears on termination of the therapy.

Other gastrointestinal reactions less frequently reported were anorexia, pyrosis, flatulence, and constipation. Gastrointestinal ulceration with and without hemorrhage has been reported.

Hematopoietic: Cases of autoimmune hemolytic anemia have been associated with the continuous administration of Ponstel for 12 months or longer. In such cases the Coombs test results are positive with evidence of both accelerated RBC production and RBC destruction. The process is reversible upon termination of Ponstel administration.

Decreases in hematocrit have been noted in 2-5% of patients and primarily in those who have received prolonged therapy.

Leukopenia, eosinophilia, thrombocytopenic purpura, agranulocytosis, pancytopenia, and bone marrow hypoplasia have also been reported on occasion.

Nervous System: Drowsiness, dizziness, nervousness, headache, blurred vision, and insomnia have occurred.

Integumentary: Urticaria, rash, and facial edema have been reported.

Renal: As with other nonsteroidal antiinflammatory agents, renal failure, including papillary necrosis, has been reported. In elderly patients, renal failure has occurred after taking Ponstel for 2-6 weeks. The renal damage may not be completely reversible. Hematuria and dysuria have also been reported with Ponstel.

Other: Eye irritation, ear pain, perspiration, mild hepatic toxicity, and increased need for insulin in a diabetic have been reported. There have been rare reports of palpitation, dyspnea, and reversible loss of color vision.

OVERDOSAGE: Although doses up to 6000 mg/day have been given, no specific information is available on the management of acute massive overdosage. Should accidental overdosage occur, the stomach should be emptied by inducing emesis or by careful gastric lavage followed by the administration of activated charcoal. Laboratory studies indicate that Ponstel should be adsorbed from the gastrointestinal tract by activated charcoal. Vital functions should be monitored and supported. Because mefenamic acid and its metabolites are firmly bound to plasma proteins, hemodialysis and peritoneal dialysis may be of little value.

DOSAGE AND ADMINISTRATION: Administration is by the oral route, preferably with food.

The recommended regimen in acute pain for adults and children over 14 years of age is 500 mg as an initial dose followed by 250 mg every six hours as needed, usually not to exceed one week.

For the treatment of primary dysmenorrhea, the recommended dosage is 500 mg as an initial dose followed by 250 mg every 6 hours, starting with the onset of bleeding and associated symptoms. Clinical studies indicate that effective treatment can be initiated with the start of menses and should not be necessary for more than 2 to 3 days.

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NEW ONCE-A-DAY DOSAGE PROLOPRIM® (trimethoprim) 100 mg Scored Tablets

**SIMPLY PRESCRIBE TWO
TABLETS Q.D. FOR 10 DAYS.**

Before prescribing PROLOPRIM, please consult complete prescribing information. The following is a brief summary:

INDICATIONS AND USAGE: For the treatment of initial episodes of uncomplicated urinary tract infections due to susceptible strains of the following organisms: *Escherichia coli*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *Enterobacter* species and coagulase-negative *Staphylococcus* species, including *S. saprophyticus*. Cultures and susceptibility tests should be performed to determine the susceptibility of the bacteria to trimethoprim. Therapy may be initiated prior to obtaining the results of these tests.

CONTRAINDICATIONS: Proloprim is contraindicated in individuals hypersensitive to trimethoprim and in those with documented megaloblastic anemia due to folate deficiency.

WARNINGS: Experience with trimethoprim alone is limited, but it has been reported rarely to interfere with hematopoiesis, especially when administered in large doses and/or for prolonged periods. The presence of clinical signs such as sore throat, fever, pallor or purpura may be early indications of serious blood disorders. Complete blood counts should be obtained if any of these signs are noted in a patient receiving trimethoprim and the drug discontinued if a significant reduction in the count of any formed blood element is found.

PRECAUTIONS:

General: Trimethoprim should be given with caution to patients with possible folate deficiency. Folate may be administered concomitantly without interfering with the antibacterial action of trimethoprim. Trimethoprim should also be given with caution to patients with impaired renal or hepatic function.

Pregnancy: Teratogenic Effects: Pregnancy Category C.

Trimethoprim has been shown to be teratogenic in the rat when given in doses 40 times the human dose. In some rabbit studies, an overall increase in fetal loss (dead and resorbed and malformed conceptuses) was associated with doses 6 times the human therapeutic dose. While there are no large well-controlled studies on the use of trimethoprim in pregnant women, Brumfitt and Pursell* reported the outcome of 186 pregnancies during which the mother received either placebo or trimethoprim in combination with sulfamethoxazole. The incidence of congenital abnormalities was 4.5% (3 of 66) in those who received placebo and 3.3% (4 of 120) in those receiving trimethoprim plus sulfamethoxazole. There were no abnormalities in the 10 children whose mothers received the drug during the first trimester. In a separate survey, Brumfitt and Pursell also found no congenital abnormalities in 35 children whose mothers had received trimethoprim plus sulfamethoxazole at the time of conception or shortly thereafter. Because trimethoprim may interfere with folic acid metabolism, Proloprim should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Trimethoprim is excreted in human milk. Because trimethoprim may interfere with folic acid metabolism, caution should be exercised when Proloprim is administered to a nursing mother.

Pediatric Use: The safety of trimethoprim in infants under 2 months has not been demonstrated. The effectiveness of trimethoprim has not been established in children under 12 years of age.

ADVERSE REACTIONS: The adverse effects encountered most often with trimethoprim are rash and pruritus. Other adverse effects reported involved the gastrointestinal and hematopoietic systems.

Dermatologic Reactions: Rash, pruritus and exfoliative dermatitis. At the recommended dosage regimens of 100 mg b.i.d. or 200 mg q.d., each for 10 days, the incidence of rash is 2.9% to 6.7%. In clinical studies which employed high doses of Proloprim, an elevated incidence of rash was noted. These rashes were maculopapular, morbilliform, pruritic and generally mild to moderate, appearing 7 to 14 days after the initiation of therapy.

Gastrointestinal Reactions: Epigastric distress, nausea, vomiting, and glossitis.

Hematologic Reactions: Thrombocytopenia, leukopenia, neutropenia, megaloblastic anemia, and methemoglobinemia.

Miscellaneous Reactions: Fever, elevation of serum transaminases and bilirubin, and increases in BUN and serum creatinine levels.

DOSAGE AND ADMINISTRATION: The usual oral adult dosage is 100 mg of Proloprim every 12 hours or 200 mg of Proloprim every 24 hours, each for 10 days.

The use of trimethoprim in patients with a creatinine clearance of less than 15 ml/min is not recommended. For patients with a creatinine clearance of 15 to 30 ml/min, the dose should be 50 mg every 12 hours. The effectiveness of trimethoprim has not been established in children under 12 years of age.

*Brumfitt W and Pursell R: Trimethoprim/Sulfamethoxazole in the Treatment of Bacteremia in Women. *J Int Dis Suppl* 128: S657-S663, 1973.

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2. Jordan PA, Irvani A, Richard GA, et al: Urinary tract infection caused by *Staphylococcus saprophyticus*. *J Infect Dis* 142: 510-515, 1980.

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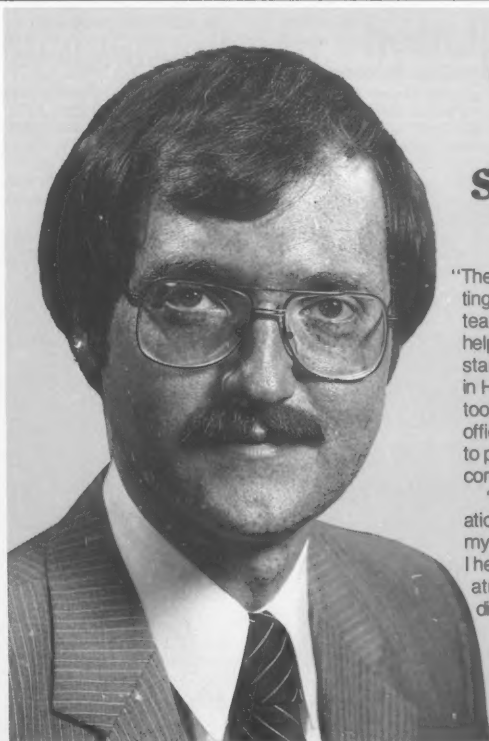
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